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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/060,047	04/14/1998	RICHARD L. DUNN	8905.157US01	9184

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EXAMINER

WEBMAN, EDWARD J

ART UNIT

PAPER NUMBER

1616

DATE MAILED: 08/23/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>
	09/060,047	DUNN, RICHARD L.
	<b>Examiner</b>	<b>Art Unit</b>
	Edward J. Webman	1616

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### **Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

1)  Responsive to communication(s) filed on 27 May 2005.

2a)  This action is **FINAL**.                    2b)  This action is non-final.

3)  Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

4)  Claim(s) 1-3,14-19 and 28-32 is/are pending in the application.  
4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

5)  Claim(s) \_\_\_\_\_ is/are allowed.

6)  Claim(s) 1-3,14-19 and 28-32 is/are rejected.

7)  Claim(s) \_\_\_\_\_ is/are objected to.

8)  Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

9)  The specification is objected to by the Examiner.

10)  The drawing(s) filed on \_\_\_\_\_ is/are: a)  accepted or b)  objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)  The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)  Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a)  All    b)  Some \* c)  None of:  
1.  Certified copies of the priority documents have been received.  
2.  Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3.  Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1)  Notice of References Cited (PTO-892)
- 2)  Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3)  Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 7/6/04.

4)  Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_ .

5)  Notice of Informal Patent Application (PTO-152)

6)  Other: \_\_\_\_ .

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-3, 14-15, 19, 28-32 are rejected under 35 U.S.C. 102(b) as being anticipated by Yamamoto et al

Yamamoto et al teach a W/O emulsion composed of a water soluble drug containing solution as the inner aqueous phase and a polymer containing solution as the oil phase (abstract). Polylactic acid is disclosed (column 5 line 2). Ethyl Acetate is specified (column 5 lines 58-59). Plural organic solvents are specified (column 5 line 60). The second organic solvent is broadly interpreted as a non-polymeric material in claim 28. Anti-inflammatory agents are disclosed (column 3 lines 21-22). A polymer concentration up to 80% is specified. Starch is disclosed (column 4 line 41). The examiner takes judicial notice under MPEP 2144.03 that starch is well known in the art as an excipient. The examiner notes that in Yamamoto et al, the drug retaining substance is optional (column 4 lines 17-20).

The rejection over Okada et al has been dropped because it is merely redundant. The examiner agrees that the last two lines in claim 1 do not constitute an intended use. As to the claimed property of forming a solid implant when the composition contacts an aqueous medium, the anticipatory composition must possess said property because it is the same composition as claimed. Applicant argues that, in Yamamoto et al, the WO emulsion is added to a third aqueous phase without formation of a solid, but rather the

Art Unit: 1616

formation of a W/O/W emulsion. However, the amount of water in that third phase compared to the amount of water in which applicant's emulsion solidifies is at issue. In example 1 of Yamamoto et al, 0.3 ml of an aqueous solution of active emulsified with a solution of 3.5 g polylactic acid in 4 ml of methylene chloride. The emulsion is then dispersed in a 500 ml aqueous 5% solution of polyvinyl alcohol to form a W/O/W emulsion. In applicant's example 1, beginning on page 25 of his specification, 1 ml of a 40% polymer solution of polymer in propylene carbonate is added to 0.5 ml of water to make an emulsion which in turn is added to 5 ml of phosphate buffer to form a solid. It is argued that the Yamamoto et al emulsion, if added to 5 ml phosphate buffer rather than the 500 ml aqueous solution, will also form a solid because the composition is the same as that claimed. The volume of the aqueous phase in example 1 of Yamamoto et al is larger than that in applicant's example 1 by a factor of 100. Therefore, the comparison to applicant's example is inapt.

Claim 28 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 28 it is unclear as to whether the "non-polymeric material" is the previously recited organic solvent or a third component in addition to that solvent.

Claims 1-15, 19, 28-32 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for polymers of an inherent (intrinsic?)

viscosity of 0.2 dL/g, does not reasonably provide enablement for any polymer. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims. On page 17, line 26 applicants disclose the viscosity cited above. No other is disclosed for the claimed invention. It appears that a polymer with too high a viscosity will preclude emulsification, whereas a polymer with too low a viscosity will not form the solid as claimed. That is, it appears that the viscosity of the polymer is critical to the invention. However, applicants claim polymers of any viscosity. Thus, the breadth of the claims exceeds the scope of the disclosure.

No claims allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Edward J. Webman whose telephone number is 571-272-0633. The examiner can normally be reached on M-F from 8 AM to 5 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, G. Kunz, can be reached on 571-272-0887. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should

Art Unit: 1616

you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



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